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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,804	06/07/2001	Karoly Nikolics	P0576P1C2	1198

9157 7590 07/11/2003

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/19/03☒ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 7-9, 16-20, 28, 42, 43, 47, 48, 52-62 is/are pending in the application.
☐ Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 7-9, 16-20, 28, 42, 43, 47, 48, 52-62 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Part III: Detailed Office Action

Claims 7-9, 16-20, 28, 42-43, 45, 47, 48, 52-59 and 60-62 are pending and under consideration.

5 **Formal Matters:**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicants traversal of this requirement in paper number 14, received 5/23/03, has been fully considered but is not deemed persuasive, as there is no longer any claim to the generic invention; all pending claims are restricted to the elected species,
10 FSH-R.

Claims 28, 54 and 55 are objected to for failing to further limit the claims from which they depend. All the limitations of those claims are previously recited in the chain of dependency from which they descend.

15 Appropriate correction is required.

Double Patenting Rejections:

20 The rejection of claims 7-9, 16-20, 28, 42-43, 45, 47, 48 and 52-59 under the judicially created doctrine of obviousness-type double patenting is withdrawn in view of the amendments to the claims.

Objections and Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

25 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 61 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The vector of part (a) of the claim is not required to contain the DNA molecule of claim 60, hence there is no antecedent basis for "said vector comprising the recombinant DNA molecule of claim 60" as recited in part (b) of the claim.

5 The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10

Claims 7-9, 16-20, 28, 42-43, 45, 47, 48, 52-59 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15 As stated in the previous Office Action, the claims are broadly drawn to any DNA encoding FSH receptor, including both genomic and non-genomic DNA, such sequences from any possible species that has such receptors, or any DNA encoding any such receptor, whether such is naturally occurring or not (i.e. any possible protein having FSH receptor activity). However, the actual disclosure found in the specification is extremely narrow, being limited to actual coding sequences
20 for rat LH/CG and FSH receptors. It is noted that applicants have amended the claims to recite that the claimed DNA must be capable of hybridizing at 42 (or 50) degrees in 20% or 50% formamide to the DNA of SEQ ID NO: ID NO: 5. However, there is no adequate written description of species representative of the breadth of such claims. As there is conservation among the different members of the glycoprotein hormone receptor family in particular, and among G protein receptors in general,
25 a large number of naturally occurring receptors might be expected to meet the hybridization limitation. Further, as stated previously and above, the claims are not limited to naturally occurring species. The description of a single species within the scope of the claims, cDNA encoding rat testicular FSH receptor, is not sufficient to describe the broad range of DNAs being claimed. The Examiner further notes that recitation of hybridization conditions is merely an assay to determine

whether a DNA might fall within the metes and bounds of the claims, and not a description of DNAs that are being claimed. The claims are drawn to innumerable possible species, whereas the specification discloses only a single means, rat cDNA encoding rat FSH receptor. The concept that there might be related molecules possible is not the same as the conception of particular molecules.

5 Accordingly, the rejection is maintained for reasons of record.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

10 A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15 Claims 7-9, 16-20, 28, 42-43, 45, 47, 52-59 and 60-62 are rejected under 35 U.S.C. 102(a) as being anticipated by Sprengel et al., Mol. Endocrinol. 4:525-530 (1990), for reasons of record in the previous Office Action at pages 5-6.

20 Applicants traversal regarding the availability date of the Sprengel reference has been fully considered but is not deemed persuasive. The date of public availability is the date that the first copy of the journal was *released* to the public, not the date that an unidentified library attached a sticker to their copy. It cannot be determine what library possessed that copy, what day they actually received the copy, nor is it likely that their copy was received on the day that the journal was mailed by the publisher. Accordingly, applicants argument is not persuasive.

25 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

30 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 48 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Sprengel et al. for reasons cited in the previous Office Action. Applicants arguments have been fully considered but are not deemed persuasive for reasons cited above with respect to the rejection under 35 U.S.C. § 102(a).

Advisory Information:

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 5:00 A.M. to 9:30 P.M.

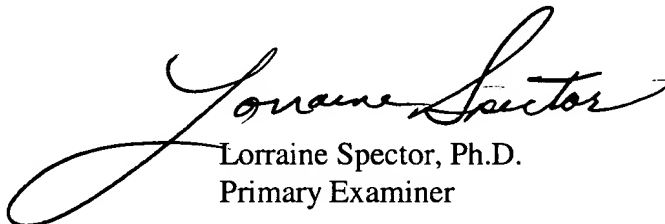
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, can be reached

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at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.



Lorraine Spector, Ph.D.
Primary Examiner

09/877804.2
7/10/03